

**Pharmacy Policy**

**Calcitonin-Gen Related Peptide (CGRP) Inhibitors - Unified Formulary**

**Policy Number:** 9.220

**Version Number:** 2.0

**Version Effective Date:** 6/1/2021

<p>Product Applicability <input type="checkbox"/> All Plan+ Products</p>	
<p><b>Well Sense Health Plan</b></p> <p><input type="checkbox"/> New Hampshire Medicaid</p>	<p><b>Boston Medical Center HealthNet Plan</b></p> <p><input checked="" type="checkbox"/> MassHealth - MCO</p> <p><input checked="" type="checkbox"/> MassHealth - ACO</p> <p><input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p>

Note: Disclaimer and audit information is located at the end of this document.

**Prior Authorization Policy**

**Reference Table:**

Drugs that require PA	No PA
Aimovig® (erenumab-aooe)	
Ajovy® (fremanezumab-vfrm for migraine prophylaxis) <sup>PD</sup>	
Emgality® (galcanezumab-gnlm for migraine prophylaxis)	
Emgality® (galcanezumab-gnlm for cluster headaches) <sup>PD</sup>	
Vyepti® (eptinezumab-jjmr)	

PD=preferred drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

**Procedure:**<sup>1-7</sup>

<b>Approval Diagnosis:</b>	<b>Cluster Headaches: Emgality®</b> <b>Migraine Prophylaxis: Aimovig®, Ajovy®, Emgality®, Vyepti®</b>
<b>Migraine Prophylaxis</b>	Prescriber provides documentation of ALL of the following:

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<p><b>Ajovy</b><sup>®</sup> (fremanezumab-vfrm)</p>	<ol style="list-style-type: none"> <li>1. Appropriate diagnosis</li> <li>2. Member is <math>\geq 18</math> years of age</li> <li>3. Appropriate dose</li> <li>4. Migraine frequency <math>\geq 4</math> days per month</li> <li>5. Inadequate response or adverse reaction to ONE of the following or contraindication to ALL of the following (history of claims is NOT sufficient for failed trial)*: <ol style="list-style-type: none"> <li>a. atenolol</li> <li>b. metoprolol</li> <li>c. nadolol</li> <li>d. propranolol</li> <li>e. timolol</li> </ol> </li> <li>6. ONE of the following: <ol style="list-style-type: none"> <li>a. Inadequate response or adverse reaction to ONE of the following (history of claims is NOT sufficient for failed trials): <ol style="list-style-type: none"> <li>i. amitriptyline†</li> <li>ii. topiramate</li> <li>iii. valproic acid</li> <li>iv. venlafaxine</li> </ol> </li> <li>b. Contraindication to ALL oral less costly prophylactic alternatives (noted above)</li> </ol> </li> </ol> <p>Notes:</p> <p>*If a prescriber specifically documents they wish to avoid a <math>\beta</math> blocker in a member due to a concurrent diagnosis of depression, this is acceptable rationale to bypass this trial. However, avoidance of a <math>\beta</math> blocker due to risk of depression in members without a documented diagnosis of depression is not adequate rationale to bypass this trial.</p> <p>† Trials with other TCAs (e.g., nortriptyline, protriptyline) will be considered acceptable in place of amitriptyline</p> <p>Previous prior authorizations for Botox<sup>®</sup>, for migraine prophylaxis, should be end-dated if member is approved for a CGRP Inhibitor. These should not be used concomitantly. Please call office to inform them of the above.</p>
<p><b>Approval Criteria:</b></p> <p><b>Migraine Prophylaxis</b></p> <p><b>Aimovig</b><sup>®</sup> (erenumab-aooe)</p> <p><b>Emgality</b><sup>®</sup> (galcanezumab-gnlm) 120 mg/mL syringe</p> <p><b>Vyepti</b><sup>®</sup> (eptinezumab-jjmr)</p>	<p>Prescriber provides documentation of ALL of the following:</p> <ol style="list-style-type: none"> <li>1. Appropriate diagnosis</li> <li>2. Member is <math>\geq 18</math> years of age</li> <li>3. Appropriate dose</li> <li>4. Migraine frequency <math>\geq 4</math> days per month</li> <li>5. Prescriber is a neurologist or a neurology consult is provided</li> <li>6. Inadequate response or adverse reaction to ONE of the following or contraindication to ALL of the following (history of claims is NOT sufficient for failed trial)*: <ol style="list-style-type: none"> <li>a. atenolol</li> <li>b. metoprolol</li> <li>c. nadolol</li> <li>d. propranolol</li> <li>e. timolol</li> </ol> </li> <li>7. Inadequate response or adverse reaction to ONE of the following or contraindication to ALL of the following (history</li> </ol>

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	<p>of claims is NOT sufficient for failed trials):</p> <ol style="list-style-type: none"> <li>i. amitriptyline†</li> <li>ii. topiramate</li> <li>iii. valproic acid</li> <li>iv. venlafaxine</li> <li>v. Botox®</li> </ol> <p>8. Inadequate response, adverse reaction or contraindication to Ajovy® (History of claims is NOT sufficient for failed trial)</p> <p>Notes:</p> <p>*If a prescriber specifically documents they wish to avoid a β blocker in a member due to a concurrent diagnosis of depression, this is acceptable rationale to bypass this trial. However, avoidance of a β blocker due to risk of depression in members without a documented diagnosis of depression is not adequate rationale to bypass this trial.</p> <p>† Trials with other TCAs (e.g., nortriptyline, protriptyline) will be considered acceptable in place of amitriptyline</p> <p>Previous prior authorizations for Botox®, for migraine prophylaxis, should be end-dated if member is approved for a CGRP Inhibitor. These should not be used concomitantly. Please call office to inform them of the above.</p>
<p><b>Approval Criteria:</b></p> <p><b>Cluster Headache Emgality®</b> (galcanezumab-gnlm) 100 mg/mL syringe</p>	<p>Prescriber provides documentation of ALL of the following:</p> <ol style="list-style-type: none"> <li>1. Appropriate diagnosis</li> <li>2. Member is ≥ 18 years of age</li> <li>3. Appropriate dose</li> <li>4. Prescriber is a neurologist or a neurology consult is provided</li> </ol>
<p><b>Denial Criteria:</b></p>	<p>Cases that do not meet the approval criteria will be denied.</p> <p>If a request is denied and the prescriber has additional clinical documentation, a <b>new</b> prior authorization request must be submitted.</p>
<p><b>Duration/Quantity of Authorization:</b></p>	<p><b>For Migraine Prophylaxis and Cluster Headache:</b> Initial approval may be granted for <b>3 months</b>.</p>
<p><b>Recertification Criteria:</b></p>	<p><b>For Migraine Prophylaxis:</b> Resubmission by prescriber will infer a positive response to therapy and request can be recertified for <b>6 months</b>.</p> <p><b>For Cluster Headache:</b> Resubmission will need to document that member is still actively having a cluster headache and that member has been initiated on prophylactic therapy for the cluster headache (e.g., verapamil, topiramate, triptans, steroids, etc.) or rationale why this is not appropriate. Request can be recertified for <b>3 months</b></p>

### Appendix:

**Stability**

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Stability on any of the CGRP Inhibitors is not a reason to bypass approval criteria. Please outreach to office to gather information necessary for approval.

**Grandfathering**

Information is not applicable.

**Applicable Coding:**

Code	Medication
J3590	Vyepti (eptinezumab-jjmr Injection)- Unclassified Biologics

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

**Policy Revisions History**

Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	Created policy for CGRP Inhibitors for MH Unified Formulary	1/1/2021	P&T Committee
02/11/2021	P&T annual review. Removed references to Vyepti only being approved via medical benefit, because we also allow it through pharmacy.	6/1/2021	P&T Committee

**Next Review Date**

2/2022

**Other Applicable Policies**

**Reference to Applicable Laws and Regulations, If Any**

**Disclaimer Information**

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Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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